



DECLARATION OF CONFORMITY
DOC-20011

SRN: US-MF-000007934

Basic UDI 006074TF1018_SkinFixSZ

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

Skin Fixation Devices

Product Name:	Skin Fixation Devices
Model Number or Designator:	See attached
Control Designator:	DOC-20011 8-Sept-2021
Device Classification:	Class 1, Rule 1, according to the European Medical Device Regulation 2017/745, Annex VIII
EMDN Nomenclature code (EMDN)	EMDN: M030302, Protection System
Global Medical Device Nomenclature Code (GMDN)	GMDN: 44990, Skin-cover adhesive strip
Universal Medical Device Nomenclature System (UMDNS)	UMDNS code: 10028, Adhesive strips, hypoallergenic
Product Options/Accessories:	N/A

The object of the declaration described is in conformity with the provisions of: Regulation (EU) MDR 2017/745, EC conformity declaration is according to Annex IX Quality Management System

The Manufacturer is certified by the Notified Body listed below to ISO 13485:2016 & EN ISO 13485:2016 Quality Management System.

Quality Certificate Number: MD 608599 Expiry: 04-March-2024
Notified Body:

BSI Group Inc.,
Notified Body CE 2797
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands
www.bsigroup.com

Authorized EU Representative:

MT Promedt Consulting GmbH
Altenhofstasse 80
D-66386 St. Ingbert
Germany

Revision: 2



Authorized Signature and function
Printed Name: Rob Yamashita, VP Regulatory

Date of Issue: 08-September-2021
Place of Issue: Regulatory Office, SunMed
Grand Rapids, Michigan, 49544 USA

This declaration of conformity is issued under the sole responsibility of Salter Labs. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All technical documentation is retained at the premises of the manufacturer/technical documentation location.



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UDIs	Model Number	Model Description
00607411001024 10607411001021	1005-0 1005-0-25	Tender Grip, Cannula fixation device
10607411001038	1006-0-100	Tender Grip, Cannula fixation device
00607411001147 10607411001144 20607411001141	1007-0 1007-0-10 1007-0-25	Tender Grip, Infant Cannula fixation device
00607411001154 10607411001151 20607411001158	1008-0 1008-0-10 1008-0-25	Tender Grip, Newborn Cannula fixation device
00607411001048 10607411001045	1016-0 1016-0-50	E-Z Wrap™ Soft, closed cell foam tubes designed to prevent ear chafing.
00607411891717 10607411891714	1017-0 1017-0-25	E-Z Wrap™ Mask Cushions. Soft, closed cell foam cushions designed to prevent ear chafing.
00607411 891113 10607411891110	1217-0 1217-0-25	Hydrocolloid Strips
10607411007313	MW100-0-120	Mini Whiskers securement device
10607411007320 10607411007337	SS100P-0-80 SS100P-0-1600	Silicon strips
10607411007344	SW102-0-25	Sticky Whiskers securement device